

Remarks

Claims 49, 50, 52, 53 and 56-87 are pending. Claims 49, 52, 53, 56, 57, 64 and 66 are allowed. Claims 58-63, 65, 68-82 and 84-87 have been newly cancelled without prejudice. Claims 49, 50, 64, 66, 67, 83, have been newly amended, without prejudice to any cancelled subject material. Claims 88-119 are newly added. No new matter has been entered.

Support for these amendments are found throughout the specification and in the claims as originally filed.

Allowed Claim 49 has been amended to correct punctuation only, e.g., to capitalize the first letter of the word “Chagas” in its last recitation in the instant claim.

Claim 50 which depends from allowed claim 49, has been amended to remove the recitation of the phrase “blood samples which comprise leukocytes which have not been fractionated into cell types”, the subject of a new matter rejection.

Allowed Claim 64 has been amended to incorporate the limitations of the claims from which it depends.

Claim 67, which depends from allowed claim 66, has been amended to remove its dependency from newly canceled claims 58 and 59, and to further depend from allowed claims 49 and 64. Claim 67 has been further amended to remove the recitation of the phrase “a blood sample which comprises leukocytes which have not been fractionated into cell types”, the subject of a new matter rejection.

Claim 83, which depends from allowed claim 66, has been amended to remove its dependency from newly canceled claims 58, 70, 76 and 77. Dependent Claim 83, which recites the limitation that the test subject be suspected of having Chagas disease, has been further amended to depend from allowed claims 49 and 64.

Newly added claims 88-92, which depend from allowed claims 64 and 66, further characterize the blood samples of test and control subjects or further characterize quantification methods. The limitations of these newly added claims 88-92 correspond to directly to the limitations recited in claims 50, 52, 53, 56 and 57, which depend from allowed claim 49.

Newly added dependent claim 93 depends from allowed claim 49, and comprises the further conclusion that an absence of Chagas disease is indicated when the expression of CDC14A in blood of the test subject is both lower with a fold-change of at least 1.5 relative to subjects with Chagas disease, and is similar relative to healthy control subjects. Support for the amendment is found in paragraphs 134 and 422 (Example 28) of the specification as published on December 2, 2004 as United States patent application 20040241729A1 by the USPTO.

Newly added dependent claim 94 depends from allowed claim 66, and comprises the further conclusion that the test subject is a candidate for not having Chagas disease when the expression of CDC14A in blood of the test subject is similar relative to healthy control subjects. Support for the amendment is found in paragraphs 134 and 422 (Example 28) of the specification as published on December 2, 2004 as United States patent application 20040241729A1 by the USPTO.

Newly added claims 95-99 depend from newly added claims 93 and 94, and further characterize the blood samples of test and control subjects or further characterize quantification methods. The limitations of these newly added claims 95-99 correspond to directly to the limitations recited in claims 50, 52, 53, 56 and 57, which depend from allowed claim 49.

Newly added independent claim 100, drawn to a method of detecting Chagas disease in a test subject, corresponds to allowable claim 49, but lacks the comparison step to controls with Chagas disease (as in allowable claim 66). Support for the amendment is found in paragraphs 134, 422 and 27 through 30, and Example 28 of the specification as published on December 2, 2004, as United States patent application 20040241729A1 by the USPTO, as well as originally filed claims 9, 10 and 12 .

Newly added independent claim 101, drawn to a method of detecting Chagas disease in a test subject, corresponds to newly added claim 49, but lacks the comparison step to controls with Chagas disease. Support for the amendment is found in paragraphs 134, 422 and 27 through 30, and Example 28 of the specification as published on December 2, 2004, as United States patent application 20040241729A1 by the USPTO, as well as originally filed claims 9, 10 and 12 .

Newly added independent claim 102, drawn to a method of screening a test subject for being a candidate for having Chagas disease, corresponds to allowed claim 66, except controls having Chagas disease are substituted for healthy controls in step (c). Support for the amendment is found in paragraphs 134, 422 and 27 through 30, and Example 28 of the specification as published on December 2, 2004, as United States patent application 20040241729A1 by the USPTO, as well as originally filed claims 9, 10 and 12 .

Newly added independent claim 103, drawn to a method of screening a test subject for being a candidate for having Chagas disease, corresponds to allowed claim 66, but claim 103 contains an additional step of comparing CDC14A mRNA levels in the blood of the test subject with subjects with Chagas disease, in addition to comparing CDC14A mRNA levels in the blood of the test subject with healthy control subjects. Claim 103 further contains an additional conclusion that the test subject is a candidate for having Chagas disease if it has a similar CDC14A RNA level as Chagas controls, in addition to having a change of at least 1.5 fold in CDC14A RNA levels in comparison to healthy controls. Support for the amendment is found in paragraphs 134, 422 and 27 through 30, and Example 28 of the specification as published on December 2, 2004, as United States patent application 20040241729A1 by the USPTO, as well as originally filed claims 9, 10 and 12 .

Newly added dependent claims 104-109, depend from newly added claims 100-103, and further characterize the blood samples of test and control subjects or further characterize quantification methods. The limitations of these newly added claims 104-108 correspond to directly to the limitations recited in claims 50, 52, 53, 56, 57 and 83, which depend from allowed claim 49.

Newly added dependent claim 110 depends from newly added claim 100, and comprises the further conclusion that an absence of Chagas disease is indicated when the expression of CDC14A in blood of the test subject is similar relative to the control subjects classified as healthy subjects. Support for the amendment is found in paragraphs 134 and 422 (Example 28) of the specification as published on December 2, 2004 as United States patent application 20040241729A1 by the USPTO.

Newly added dependent claim 111 depends from newly added claim 101, and comprises the further conclusion that an absence of Chagas disease is indicated when the expression of CDC14A in blood of the test subject is 1.5 times lower relative to the control subjects classified as subjects having Chagas disease. Support for the amendment is found in paragraphs 134 and 422 (Example 28) of the specification as published on December 2, 2004 as United States patent application 20040241729A1 by the USPTO.

Newly added dependent claim 112 depends from newly added claim 102, and comprises the further conclusion that the test subject is a candidate for not having Chagas disease if expression of CDC14A in blood of the test subject is 1.5 times lower relative to the control subjects classified as subjects having Chagas disease. Support for the amendment is found in paragraphs 134 and 422 (Example 28) of the specification as published on December 2, 2004 as United States patent application 20040241729A1 by the USPTO.

Newly added dependent claim 113 depends from newly added claim 103, and comprises the further conclusion that the test subject is a candidate for not having Chagas disease if expression of CDC14A in blood of the test subject is 1.5 times lower relative to the control subjects classified as subjects having Chagas disease, and is similar relative to the control subjects classified as healthy subjects. Support for the amendment is found in paragraphs 134 and 422 (Example 28) of the specification as published on December 2, 2004 as United States patent application 20040241729A1 by the USPTO.

Newly added dependent claims 114-119, depend from newly added claims 110-113, and further characterize the blood samples of test and control subjects or further characterize quantification methods. The limitations of these newly added claims 104-108 correspond to directly to the limitations recited in claims 50, 52, 53, 56, 57 and 83, which depend from allowed claim 49.

Specification

Example 28 in the specification has been amended to accurately reflect that the claimed biomarker CDC14A is listed in Table 3Z, and not in Table 3Y, as noted by the Examiner at page 6, second paragraph of the office action dated 06/07/2007. Erroneous reference in the specification is made to Table 3Y as listing the Chagas disease biomarkers. The correct table is Table 3Z, which recites the claimed biomarker CDC14A, as evidenced in the table legends disclosed on page 40, lines 6-9, of the specification, which correctly indicate that Table 3Y relates to schizophrenia and Table 3Z relates to Chagas disease. In addition, there are 668 Chagas biomarker genes referred to at paragraph beginning on page 94, line 25 and ending on page 95, line 4, in relevant Example 28 of the specification, and 668 genes are correspondingly listed in actual Table 3Z, whereas there are over 1,950 genes listed in Table 3Y. Thus, Applicant submits that this is merely a typographical error, and that correction of this typographical error is not new matter.

Example 28 in the specification has been amended to correctly describe Figure 27. The paragraph on page 94, lines 17-24, improperly contains the phrase “as compared with gene expression profiles from non-schizophrenic individuals”. In accordance with actual Figure 27 (sheet 27 of the drawings) and its legend described on page 17, lines 1-3, of the “BRIEF DESCRIPTION OF THE DRAWINGS” section, the paragraph on page 94, lines 17-24, otherwise properly recites “FIG. 27 shows a diagrammatic representation of gene expression profiles of blood samples from individuals who were identified as having symptomatic Chagas disease; asymptomatic Chagas disease or who were control individuals as described herein”. The typographical error appears to have been carried over verbatim by template copy-pasting from preceding Example 27, paragraph [0411] of the published application, referring to preceding Fig. 26, relating to schizophrenia. Thus, Applicant submits that this is merely a typographical error, and that correction of this typographical error is not new matter.

Claims Objection

Claims 79, 80, 81 and 82 are objected to as being a substantial duplicate of claims 71, 72, 74 and 75, respectively. Accordingly, Applicant has cancelled claims 79-82, rendering the objection of these claims moot.

Claims Rejection - 35 U.S.C. 112 1st

Claims 50, 67, 68, 69, 77, 84, 85 and 86 are rejected under 35 U.S.C. 112, 1st paragraph, as failing to comply with the written description requirement.

Claims 50, 67, 68, 69 and 77 are rejected on the grounds that the recited limitation that the blood samples comprise “leukocytes which have not been fractionated into cell types” is new matter. Although Applicant respectfully traverses, Applicant has amended Claim 50 to remove the recitation of the phrase “blood samples which comprise leukocytes which have not been fractionated into cell types”, the subject of a new matter rejection. Applicant has amended Claim 67, to remove the recitation of the phrase “a blood sample which comprises leukocytes which have not been fractionated into cell types”. Claims 68, 69 and 77 have been cancelled by Applicant.

Claims 84-86 are rejected on the grounds that the recited limitation of “wherein said fold-change is 2 or less” represents new matter. Although Applicant respectfully traverses, Claims 84- 86 have been cancelled by Applicant.

In light of the above claim amendments and remarks, Applicant respectfully requests withdrawal of the instant rejections.

Claims Rejection - 35 U.S.C. 102

Claims 58, 60, 61, 62, 63, 67, 68, 69, 71, 72, 73, 75, 79, 80 and 82 are rejected under 35 U.S.C. 102(a) and 102(b) as being anticipated by William Chittenden (2002).

Applicant respectfully traverses. However, solely for the purposes of expediting prosecution, Applicant has cancelled 58, 60, 61, 62, 63, 68, 69, 71, 72, 73, 75, 79, 80 and 82 claims, rendering their rejection moot.

Further, claim 67 which depends from allowed claim 66, has been amended to remove its dependency from newly cancelled claims 58 and 59. In light of the above claim amendments and remarks, Applicant respectfully requests withdrawal of the instant rejections.

Claims Rejection - 35 U.S.C. 102

Claims 58, 60, 61, 62, 63, 67, 68, 69, 71, 72, 73, 75, 79, 80 and 82 are rejected under 35 U.S.C. 102(a) as being anticipated by Expression Linked Polymorphism Database, (2003).

Applicant respectfully traverses. However, solely for the purposes of expediting prosecution, Applicant has cancelled claims 58, 60, 61, 62, 63, 68, 69, 71, 72, 73, 75, 79, 80 and 82, rendering their rejection moot.

Further, claim 67 which depends from allowed claim 66, has been amended to remove its dependency from newly cancelled claims 58 and 59. In light of the above claim amendments and remarks, Applicant respectfully requests withdrawal of the instant rejections.

Claims Rejection - 35 U.S.C. 103

Claims 59, 60, 61, 62, 63, 67, 68, 69, 71, 72, 73, 74, 75, 79, 80, 81 and 82 are rejected under 35 U.S.C. 103(a) as being obvious over Expression Linked Polymorphism Database, (2003), in view of Chenchik (US5,994,076).

Applicant respectfully traverses. However, solely for the purposes of expediting prosecution, Applicant has cancelled claims 59, 60, 61, 62, 63, 68, 69, 71, 72, 73, 74, 75, 79, 80, 81 and 82, rendering their rejection moot.

Further, claim 67 which depends from allowed claim 66, has been amended to remove its dependency from newly cancelled claims 58 and 59. In light of the above claim amendments and remarks, Applicant respectfully requests withdrawal of the instant rejections.

Claims Rejection - 35 U.S.C. 103

Claims 58, 59, 60, 61, 62, 63, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 82, 83, 84, 85, 86 and 87 are rejected under 35 U.S.C. 103(a) as being obvious over Dutra et al. (1997), in view of both Affymetrix GeneChip Human Genome U133 data sheet (2001) and Sharma et al. (WO98/49342).

Applicant respectfully traverses. However, solely for the purposes of expediting prosecution, Applicant has cancelled claims 58, 59, 60, 61, 62, 63, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 82, 84, 85, 86 and 87, rendering their rejection moot.

Further, claim 67 which depends from allowed claim 66, has been amended to remove its dependency from newly cancelled claims 58 and 59.

Further, claim 83 which depends from allowed claim 66, has been amended to remove its dependency from newly cancelled claims 58, 70, 76 and 77.

Conclusion

Applicant respectfully submits that the instant claims are allowable as written and respectfully request favorable action by the Examiner. No new matter is added. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Respectfully submitted,

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